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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,544	11/29/2001	Robert M. Hamilton	BRE4-M92a	8562
20995	7590	03/23/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8W

Office Action Summary

Application No.

10/020,544

Applicant(s)

HAMILTON ET AL.

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) 22-24, 31-34 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-10, 21 and 35 is/are rejected.
- 7) ☒ Claim(s) 5, 7, 11-20, 36-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "36d" in figure 7 has two elements listed as 36d has been used to designate both restrictor and a passageway. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the inhalation/exhalation selector must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8-10, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatch (4,838,257).

With respect to claim 1 Hatch discloses a CPAP apparatus for supplying breathable gas from a pressurized source to an individual's breathing appliance, which appliance has an inlet for receiving the gas and an inhalation/exhalation valve for routing the gas to the individual's lungs and the exhaled air to atmosphere, the apparatus comprising: a demand valve assembly (12) having a supply inlet port adapted

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to be connected to the pressurized source (10), an outlet port (25) adapted to be connected to the appliance's inlet (14), a reference chamber (25) and a control assembly (11, 12, 15, 16) responsive to a pressure differential pressure between a reference chamber pressure and an outlet port pressure (note role of monitor 20) for fluidly connecting and disconnecting the inlet port to and from the outlet port; and at least one adjustable back pressure regulator fluidly connected to the pressurized source and the reference chamber for setting the pressure in the reference chamber at a selected level above atmospheric pressure (note the interconnectivity of 10, 20, 54, 16 via the electronics and computer 17).

With respect to claim 2, Hatch discloses the demand valve assembly includes an outlet chamber upstream from the outlet port, the pressure in the outlet chamber being representative of a pressure in a breathing appliance inlet fluidly connected therewith (Fig. 3, sub-structure of 12 between diaphragm 42 and 14).

With respect to claim 3, Hatch discloses the demand valve assembly includes a main valve disposed between the inlet and outlet ports (42, 44, 46) wherein the control assembly causes the main valve to open and fluidly connect the inlet port to the outlet port when the outlet port pressure falls below the pressure in the reference chamber and for causing the main valve to close to fluidly disconnect the inlet from the outlet port when outlet port pressure rises to the pressure in the reference chamber (note controller 17 and the disclosure regarding how it takes pilot valve and pressure monitor feedback to modulate the valving).

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With respect to claim 4, Hatch discloses wherein the control assembly comprises a control valve (valve 11, which as a provider of the data feedback loop provides data to 17 for controlling the valves).

With respect to claim 6, Hatch discloses wherein the main valve comprises a diaphragm valve (42) with first and second actuating chambers disposed on opposite sides of the diaphragm (25, 48), the area of the diaphragm exposed to the second chamber being smaller than the area of the diaphragm exposed to the first chamber whereby the main valve will remain open when the pressure in the first chamber falls below the pressure in the second chamber by a preset amount (note that only the circumferential bulge of diaphragm 42 is exposed to 48).

With respect to claim 8, Hatch discloses the control valve comprises a diaphragm valve with the reference chamber and a second chamber disposed on opposite sides of a pressure sensing diaphragm, the second chamber being in fluid communication with the outlet port (note fluid connectivity of 11 via airway appliance).

With respect to claim 9, Hatch discloses both chambers of the main diaphragm valve are fluidly connected to the inlet port, the fluid connection to the first chamber including a restrictor for restricting the flow rate (44).

With respect to claim 10, Hatch discloses the control assembly further includes a normally closed pilot valve fluidly connected to the first chamber of the main valve to the pilot valve opening to fluidly connect the first chamber of the main valve to the second chamber of the control valve in response to the movement of the sensing diaphragm as

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a result of the pressure in the second chamber of the control valve falling below the pressure in the reference chamber (note pilot valves 15, 16).

With respect to claim 21, Hatch discloses a nozzle disposed upstream of the outlet port and in an educting relationship with the outlet chamber so that the pressure in the outlet chamber varies with the flow rate of gas through the nozzle to compensate for pressure losses between the outlet port and the breathing appliance inlet.

With respect to claims 35, note rejection of claims 1-3 above.

Allowable Subject Matter

Claims 5, 7, 11-20, and 36-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 7/23/04 have been fully considered but they are not persuasive. While the examiner in the interview did agree that Hatch was not a pneumatically controlled system and therefore readable over the claims, after review of the amendment applicant has not distinguished in the body of the claim any structural differences which distinguish over the device of Hatch, the only mention of a pneumatically controlled CPAP is in the preamble of the claims, therefore the rejection of Hatch is being maintained, note rejection above.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-

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4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Examiner
Art Unit 3743
March 20, 2005